U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE
SUBCOMMITTEE ON ENVIRONMENT, TECHNOLOGY, AND STANDARDS

HEARING CHARTER
"Small Business Innovation Research: What is the Optimal Role of Venture Capital?"
Tuesday, June 28, 2005
3:00 P.M – 5:00 P.M.
2318 Rayburn House Office Building

PURPOSE:

On Tuesday, June 28, at 3:00 p.m. the House Science Committee's Subcommittee on Environment, Technology, and Standards will hold a hearing to review the Small Business Innovation Research (SBIR) program, focusing on issues associated with awarding SBIR grants to small businesses owned, or partly owned, by venture capital firms.

WITNESSES:

Panel I:

Representative Sam Graves (R-MO), sponsor of H.R. 2943, the *Save Biotechnology Innovative Research Act of 2005,* introduced on June 16, 2005. The bill would allow more expansive venture capital participation in small businesses eligible for SBIR awards.

Panel II:

Ms. Ann Eskesen, President, Innovation Technology Institute, Swampscott, MA. The Innovation Technology Institute is a clearinghouse for information on SBIR technology and outcomes and supports collaboration between technology companies. Ms. Eskesen believes that venture capital is critical to technology development, but that SBIR rules should not be significantly changed to favor venture capital firms.

Dr. Ron Cohen, CEO of Acorda Technologies, Hawthorne, NY. Acorda Technologies is a small biotechnology company that develops treatments for neurological disorders. Dr. Cohen believes that venture capital investment in SBIR companies should not be restricted.

Mr. Jonathan Cohen, President and CEO, 20/20 Gene Systems, Rockville, MD. 20/20 Gene Systems is a small biotechnology company that develops diagnostic methods and test kits with applications in drug development and testing, homeland security, and disease diagnosis. Mr. Cohen believes that venture capital investment in SBIR companies should be limited.

Dr. Dr. Carol Nacy, CEO, Sequella Inc., Rockville, MD. Sequella develops diagnostics, therapeutics, and vaccines for tuberculosis. Dr. Nacy believes that venture capital investment in SBIR companies should not be restricted.

Dr. Frederic Abramson, President and CEO of AlphaGenics, Inc. of Rockville, MD. AlphaGenics is a small biotechnology company that focuses on the interactions between nutrition, metabolism, human development, and gene expression. Dr. Abramson believes that venture capital investment in SBIR companies should be limited.

OVERARCHING QUESTION:

Should companies that are majority-owned by venture capital firms be allowed to compete for SBIR awards? If such a change were made, what impact would it be likely to have on the SBIR program?

RECENT DEVELOPMENTS

A spirited debate is underway in the research and venture capital communities on whether it is appropriate for SBIR awards to be given to small companies that are majority-owned by venture capital (VC) companies.

On December 3, 2004, the Small Business Administration (SBA) issued a final rule saying that to be eligible for an SBIR award, an entity must be a for-profit business at least 51 percent owned and controlled by one or more U.S. individuals, or 51 percent owned and controlled by another small business owned and controlled by Americans. Typically, VC firms are not controlled by individuals, but rather by entities such as private and public pension funds, financial and insurance investors, and endowments and foundations.

Also on December 3, 2004, to get more guidance on the issue, SBA published an Advance Notice of Proposed Rulemaking (ANPR), seeking additional public comment on the VC issue. In particular, SBA is seeking comment on what the impact of maintaining or changing the current rules would have on the eligibility and composition of the SBIR applicant pool, which firms would benefit or suffer from a change, and whether the broader participation of VC firms would lead to multiple award winners at the expense of innovation and diversity.

SBA has followed up the ANPR with a series of public meetings around the United States to obtain further public comment on the role of VCs in SBIR. These meetings will continue through June 30, 2005. Meanwhile, identical bills[1] have been introduced in the House and the Senate to change the eligibility rules for SBIR. The legislation would allow a firm to participate in SBIR even if a consortium of VC firms controlled a majority stake as long as no single VC firm held more than a 49 percent stake in the company. The legislation is supported by the Biotechnology Industry Organization (BIO) and the National Venture Capital Association (NVCA).

Proponents of changing the current rule argue that VC firms are a major source of financing in certain industries, such as biotechnology, and that VC support can help a firm continue research and commercialize products. Opponents contend that VC firms are often run by large

[1] S. 1263, *Save America's Biotechnology Innovative Research Act of 2005*, introduced by Senator Bond, and H.R. 2943, *Save Biotechnology Innovative Research Act of 2005*, introduced by Representative Graves.

corporations. Therefore, opponents argue, small businesses that are controlled by VC firms should not be seen as independent small businesses in need of special research funding, but rather as arms of large corporations that do not merit SBIR support.

BACKGROUND

The SBIR Program

SBIR was established in 1982 by the *Small Business Innovation Development Act* [P.L. 97-219] to increase the participation of small, high technology firms in Federal research and development (R&D) activities. SBIR has been reauthorized twice since its original enactment, and the current program authorization is scheduled to sunset in 2008. The Science Committee and the Small Business Committee share jurisdiction over the program in the House.

Under SBIR, departments and agencies with R&D budgets of $100 million or more are required to set aside 2.5 percent of their R&D budgets to sponsor research at small companies through the SBIR program. Currently, 11 departments and agencies sponsor SBIR programs: the Departments of Defense (DoD), Commerce, Education, Health and Human Services, Housing and Urban Development, Homeland Security, Transportation, Energy, and the Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation.

Each agency runs its own SBIR program, emphasizing research areas of interest to the particular agency. But SBA establishes broad policy guidelines for the SBIR program. SBA monitors program implementation and reports to Congress on the conduct of the separate departmental and agency activities.

Small businesses are eligible for SBIR awards if they are independently owned and operated for-profit companies, not dominant in the field of research proposed, and employ fewer than 500 people.

From its inception in 1983 to 2003, the most recent year for which reliable is available, over $15.2 billion in SBIR awards have been made for more than 76,000 research projects. In fiscal year 2003, SBIR made 6,224 awards, totaling $1.66 billion.

The Venture Capital Issue

The current dispute over VC funding began on January 10, 2001, when the SBA Office of Hearings and Appeals issued a ruling against the majority ownership of SBIR companies by VC firms. This ruling was based on the appeal of CBR Laboratories, Inc., of Boston, Massachusetts, to the rejection of its application for SBIR funding by the National Institutes of Health. CBR Laboratories' grant application had been rejected because a VC firm held a controlling interest (i.e., more than 51 percent stake) in CBR Laboratories. The ruling made by the Administrative Law Judge stated that VC firms were not "individuals," i.e., "natural persons," and therefore SBIR agencies could not give SBIR grants to companies in which VC firms had a controlling interest. The biotechnology and VC industries were dismayed by this ruling, seeing it as a new interpretation of the VC-small business relationship by SBA, which had treated VC firms as individuals up to this decision.

Advocates for Expanded VC Participation in SBIR-eligible Companies
The biotechnology industry is the strongest advocate for unrestricted VC affiliation with SBIR-funded companies. Advocates argue that the SBA rule at best creates a meaningless barrier to private-sector investment that inhibits growth of budding companies, and at worst blocks the translation of new discoveries into life-saving products for numerous fatal diseases. They point out that biotechnology R&D is capital-intensive and the involvement of VC money is critical to bring drugs through the development phase to market. BIO and NVCA have taken the official position that eligibility for SBIR awards should be expanded to include small companies that are majority owned by a consortium of VC firms.

Advocates for Limited VC in SBIR
However, the biotechnology industry is not entirely united in its opposition to SBA's policy. Some biotechnology experts and company representatives argue that, if SBA regulations allowed more VC-backed companies to apply for SBIR grants, they would crowd out completely independent small research companies run or owned by individuals. They also point out that SBIR-eligible companies are currently able to attract VC backing without giving away a majority stake, and therefore it is not necessary to expand the role of VC.

Beyond the biotechnology industry, some companies and small business advocates point out that many large companies, such as Intel, have set up VC funds as a means of investing in, and ultimately buying promising new companies that develop breakthrough technologies. They argue that if the Federal government funded small businesses backed by such VC funds, the SBIR program could end up subsidizing the acquisition of small businesses by big businesses. This position is held by the Small Business Technology Coalition (SBTC), for example.

History and Background of Small Business Innovation Research (SBIR) program
The argument for the SBIR program as a whole was that while universities and large firms could compete successfully for Federal research and development contracts and grants, small companies were at a disadvantage in spite of their great potential to contribute to the nation's science base. SBIR was designed to redress this disadvantage.

In 2001, the most recent reauthorization of SBIR, the *Small Business Reauthorization Act* [P.L. 106-554] required a study by the National Academy of Sciences review of the largest SBIR programs to find out, for example, if SBIR research was leading to new products in the marketplace. The Act also required SBA to establish databases of SBIR activity to help track and assess the performance of the SBIR program, and encouraged SBIR agencies to do a better job of partnering with states.

The SBIR program is structured in three phases. Phase I awards (up to $100,000) fund research projects designed to evaluate the feasibility, and the scientific and technical merit of an idea. Phase II awards (up to $750,000) provide additional funding for Phase I projects that have demonstrated potential for successful development. Phase III is a not formally funded by the Federal government, although some agencies have begun experimenting with Phase III awards. Phase III is where private-sector investment and support is supposed to step in and bring an innovation to market. However, Phase III funds may include follow-up contracts with Federal

agencies for the production of Phase II innovations. This is particularly true in the case of the Department of Defense.

SBIR Legislation in the 109th Congress

On June 16, 2005, Senator Bond and Representative Graves introduced identical bills, S. 1263 and H.R. 2943, the *Save Biotechnology Innovative Research Act of 2005*.

This legislation would expand eligibility for SBIR awards to include small businesses that are majority owned by a consortium of VC firms as long as no one VC firm held a majority stake. The legislation further would require that, for a small company to remain eligible, the participating VC firm cannot be owned by a large company. The legislation would allow start-up companies (defined as companies with sales of less than $3 million, and no positive cash flow from operations) to be eligible for SBIR no matter how large a stake a VC firm controlled in them. The legislation has been endorsed by BIO and the NVCA.

Issues Raised in GAO Reports on SBIR

The Government Accountability Office (GAO) has issued a number of reports over the years that assess various aspects of SBIR. The following are the more significant issues that GAO has highlighted:

- **Commercialization Rates**

In 1991, GAO gave SBIR a generally favorable review, stating that SBIR "clearly is doing what Congress asked it to do in achieving commercial sales and developmental funding from the private sector." GAO reported that an SBA study found that approximately one in four SBIR projects resulted in the sale of new commercial products or processes. GAO issued another report in 1992 in which it addressed Phase III activity, saying that although not enough time had elapsed since the beginning of the program for SBIR projects to fully mature, it appeared that SBIR projects were obtaining Phase III funding (an indicator of commercialization potential), with commercial activity totaling $1.1 billion in sales since the beginning of the program.

- **Multiple Award Winners**

In 1999, GAO testified before the House Science Subcommittee on Technology, summarizing the findings of its report on SBIR. In this testimony, GAO reported that the 25 most frequent winners of SBIR grants, representing less that one percent of the companies in the program, received about 11 percent of the program's awards, totaling $900 million over 14 years. GAO did note that one-third of winning applicants during a five-year period from 1993-1997 were first-time applicants, an average of 750 a year, which indicated that the program was not stagnating. What GAO focused most on, however, was the lack of consistent methods to define and track commercialization and thus evaluate the SBIR program's success, and the recognition of the fact that commercialization a) meant different things to different agencies and b) was not always consistent with the mission of the agency in question.

In its 1992 report, GAO noted that companies that received multiple Phase II grants appeared to have lower Phase III-related sales and private-sector funding than did those companies with lower numbers of Phase II awards. In addition individual companies have occasionally complained that there are companies that only do research but are not significantly involved in

commercializing research results, and are thus dependent on SBIR Phase II grants to remain operational. These firms have been given the moniker "SBIR mills." SBIR mills do not appear to be a widespread phenomenon, but because of the lack of a uniform reporting, tracking, and analytical process for SBIR, it is impossible for program managers or anyone else to assess their true extent.

- **Geographical diversity**

SBIR grants are heavily concentrated (about 40 percent of the total funding) in the states of California, Massachusetts, Virginia, Maryland, and New York, and this distribution has not changed significantly over time. Some critics have said that these concentrations are unfair and that SBIR managers should do a better job of distributing their awards geographically, and recruiting promising companies in underserved areas. Others argue that the distribution of SBIR simply reflects where clusters of research intensive companies are located. For example, Maryland receives significant amounts of SBIR funding because of the biotechnology companies clustered around the National Institutes of Health. SBA has an outreach office to publicize the SBIR program in underserved areas.

QUESTIONS FOR THE WITNESSES

All of the witnesses were asked the following question:

In your testimony, please summarize your views on the Small Business Innovation and Research (SBIR) program, and answer the following question:

1. How should venture capital ownership of small companies be treated in the consideration of SBIR applications?